## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

I

TELOMERE DIAGNOSTICS, INC., a Delaware corporation,  Plaintiff,	Civil Action No:
v.	JURY TRIAL DEMANDED
TITANOVO, INC., a Delaware corporation,	
Defendant.	

### **COMPLAINT**

Plaintiff Telomere Diagnostics, Inc. ("Plaintiff" or "TelomereDX"), by and through its undersigned counsel, hereby files the following Complaint against Defendant Titanovo, Inc. ("Defendant" or "Titanovo"), and alleges:

#### **INTRODUCTION**

- 1. TelomereDX develops and sells the TeloYears<sup>TM</sup> genetic test for determining cellular age encoded in person's DNA to help them know how well they are aging. The TeloYears<sup>TM</sup> test is based on measuring the length of telomeres, the dynamic protective caps on DNA that tend to shorten and fray with age.
- 2. TelomereDX was founded in 2010 by four scientists, including the winner of the Nobel Prize in Medicine in 2009 for pioneering work in telomere biology.
- 3. Not only are the methods used by the TeloYears<sup>™</sup> test patented and proprietary to TelomereDX, but TelomereDX has over the years invested substantial amounts of time and resources developing test procedures, test facilities, and standards and models for purposes of ensuring that its application of its proprietary testing methods provides highly accurate and

reliable results. Thanks to these efforts, the TeloYears<sup>TM</sup> test has achieved significant sales and has become the market leader.

- 4. This action arises out of competitor Titanovo stealing the patented technology used in the TeloYears<sup>TM</sup> genetic test and freeloading on TelomereDX's brand and trademarks. Rather than putting in the time and resources necessary to independently develop a system for determining cellular age, Titanovo rushed to market with a directly competing test that infringes TelomereDX's patent rights, thereby tacitly acknowledging that it lacks the proprietary technology, capabilities and expertise to compete fairly. It is then engaged in trademark infringement, false advertising and unfair competition in marketing its products.
- 5. Having stolen TelomereDX's intellectual property, Titanovo, on information and belief, has experienced difficulty providing consumers with accurate and reliable results on such core metrics as average telomere length, comparison of telomere measurements with relevant populations, and the determination of cellular age.
- 6. On information and belief, these problems stem from Titanovo's lack of robust and validated test procedures, models, and standards and testing facilities. Titanovo has attempted to cover up these shortcomings by making false or misleading representations that (a) it is CLIA certified when, in fact, it is not and (b) it performs testing and analysis of consumers' saliva swabs in-house when, in fact, in many instances third party laboratories perform that testing and analysis. Accordingly, TelomereDX has added to this action claims seeking recovery for the harm resulting from Titanovo's false and misleading advertising and related claims for unfair competition.
- 7. The inferiority of Titanovo's test results has tarnished the reputation of TelomereDX and thereby harms the market for the patented and proprietary telomere

measurement systems that TelomereDX has worked so hard to develop. Recent publications have reported that investigators looking into the performance of TeloYears<sup>TM</sup> versus the test offered by Titanovo did not get the same results from the TeloYears<sup>TM</sup> test and the Titanovo test, and concluded from the different results that "it's not clear that the tests produce accurate results" and "telomere-measuring kits may not be reliable" (Center For Science in the Public Interest, May 25, 2017) and "results don't add up" (KPBS News, May 19, 2017). On information and belief, TeloYears<sup>TM</sup> test results, which are validated as reliable and accurate based on transparent data and modeling, are nonetheless held in lower esteem due to the unfair association with a competing Titanovo test that is not providing similarly validated, reliable and accurate results.

8. Titanovo must now be held accountable for its unlawful conduct and the substantial, and in many respects irreparable, harm inflicted on TelomereDX. Judicial intervention is required not only to recover from Titanovo significant monetary damages, penalties and fees and costs, but also to enter injunctive relief to prevent any further irreparable harm to TelomereDX's reputation and markets that will result from Titanovo's continued patent and trade mark infringement, false advertising and unfair competition.

#### THE PARTIES

- 9. Plaintiff is a Delaware corporation with its principal place of business at 3603 Haven Ave., Suite A, Menlo Park, CA 94025. As originally incorporated, Plaintiff was named Telome Health, Inc. In 2013, Plaintiff changed its name to Telomere Diagnostics, Inc.
- Defendant is a Delaware corporation, with its principal place of business at
   4922A Windy Hill Drive, Raleigh, NC 27601.

#### **JURISDICTION AND VENUE**

- 11. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 271 and 281, *et seq.*, and for false advertising and unfair competition under Lanham Act, 15 U.S.C. §§ 1051 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a)-(b).
- 12. This action also asserts state-law claims for trademark infringement, consumer fraud, and deceptive trade practices under Delaware state law, DEL. CODE ANN. tit. 6, § 3301 *et seq.*, DEL. CODE ANN. tit. 6, § 2511 *et seq.*, and DEL. CODE ANN. tit. 6, § 2531 *et seq.* that are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. This Court has supplemental jurisdiction over these claims pursuant to 28 U.S.C. § 1367(a).
  - 13. Venue is proper in this district under 28 U.S.C. §§ 1391(c) and 1400(b).
- 14. Defendant is subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Delaware Long Arm Statute. Defendant has availed itself of Delaware corporate law. In addition, on information and belief, Defendant has engaged in substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; (ii) targeting business activities towards consumers in the United States, including Delaware, through at least fully interactive commercial Internet sites and stores; and/or (iii) regularly doing or soliciting business, engaging in other persistent courses of conduct, or deriving substantial revenue from goods and services provided to individuals in Delaware.

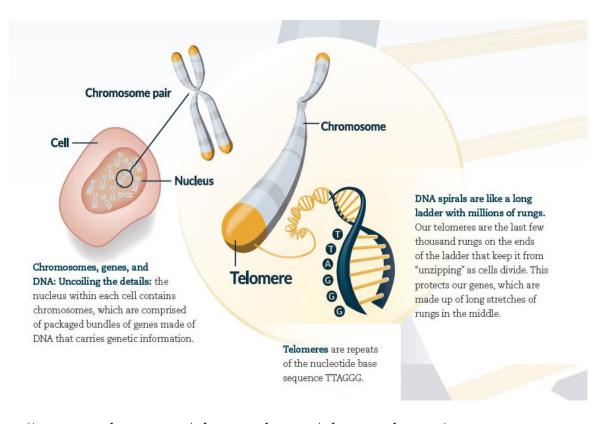
#### **BACKGROUND**

#### **Telomeres and Aging**

15. TelomereDX makes and sells directly to consumers the TeloYears<sup>TM</sup> genetic test

for a person's cellular age.

16. The TeloYears™ test measures the length of telomeres. A telomere is a section of repetitive nucleotide sequences (e.g., TTAGGG) at the end of each chromosome in a human cell. A chromosome is made up of a tightly coiled bundle of DNA within the nucleus of a cell. Within the tightly coiled bundles of DNA are genes, which carry the necessary information to form proteins. A telomere acts as protective cap on the end of a chromosome to help maintain the integrity of the genetic information during cell division, which is important to maintaining healthy cells. TelomereDX's website provides an illustration of the relationship between chromosomes and telomeres:



(https://resources.teloyears.com/what-are-telomeres/what-are-telomeres).

17. Telomeres typically are at their longest at birth and tend to grow shorter over time with increased age. Over time, upon repeated cell division, the shorter and more frayed the telomeres become – similar to what occurs to the plastic strips on shoelaces as they are used over

time. The following image from TelomereDX's website shows how telomeres (the orange ends of the chromosome) can naturally shorten over time as they protect genetic information during cell division



(https://www.teloyears.com/about-telomere-science.html).

18. There is a large body of scientific evidence on the interplay between telomere length and a person's genetics, lifestyle, environment, stress and wellness.

## **TelomereDX Acquires Leading Telomere Measurement Technology**

- 19. The TeloYears™ test measures telomere length by using a unique and proprietary quantitative polymerase chain reaction (qPCR) assay to determine average telomere length, which was invented by Richard Cawthon MD, PhD (the "Cawthon qPCR assay") and is widely regarded as the world's leading method for performing such measurements.
- 20. The foundational patent on the Cawthon qPCR assay technology was issued on April 13, 2010 to Dr. Cawthon as U.S. Patent No. 7,695,904 ("the '904 patent"), entitled "Reducing Non-Target Nucleic Acid Dependent Amplifications: Amplifying Repetitive Nucleic Acid Sequences." A copy of the '904 patent is attached as Exhibit A.

- 21. Dr. Cawthon assigned the '904 patent and related patents on telomere technologies that he developed (collectively "the Cawthon patents") to the University of Utah Research Foundation.
- 22. Thereafter, on September 1, 2010, the University of Utah Research Foundation transferred substantially all right, title and interest in the Cawthon patents to TelomereDX (then known as Telome Health, Inc.) under an Exclusive License Agreement.
- 23. Dr. Cawthon, in addition to his position as a research professor in the Department of Human Genetics at the University of Utah, is also a Scientific Advisor to TelomereDX.

#### TeloYears<sup>TM</sup> Testing

- 24. Consumers provide TelomereDX with blood samples, which are then analyzed by TelomereDX in its Silicon Valley lab using the Cawthon qPCR assay as part of the TeloYears<sup>TM</sup> test. This lab is regulated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and since 2013 has been CLIA-certified to perform high-complexity clinical testing (CLIA Certificate of Registration 05D2041002), as well as certified in numerous states, including California (Clinical Chemistry License CLF 00342713).
- 25. The TelomereDX lab measurements of average telomere length have been validated in a peer-reviewed paper, "Analytical Validation of Relative Average Telomere Length Measurement in a Clinical Laboratory Environment," published in The Journal of Applied Laboratory Medicine in April 2017. TelomereDX is the world's only telomere lab whose analytical validation of its measurement method has been published in a peer-reviewed scientific journal.
- 26. TelomereDX has invested significant time and resources developing proprietary methods to address the sensitive nature of the Cawthon qPCR assay with regard to sample

collection, storage, preparation and assay conditions. It also uses multiple standards and normalization procedures to ensure precision and accuracy of the assay.

27. The TeloYears<sup>TM</sup> test yields a highly reliable and accurate measurement of a person's average telomere length within a coefficient of variability that is typically in the 2% to 3% range, i.e. has a margin of error of 3% or less. This image is an example of the average telomere length result provided by the TeloYears<sup>TM</sup> test:

## YOUR RESULTS:

Your Average
Telomere Length is
1.02 (T/S ratio) which
puts you in the 76th
percentile. This means
that your telomeres are
longer than 76% of
men your age.^1

(https://www.teloyears.com/html/pdf/TeloYears\_TestReport\_Final.pdf (excerpted)).

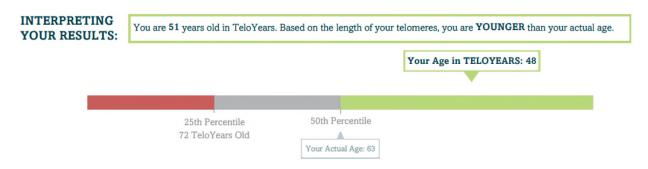
- 28. The TeloYears<sup>TM</sup> test also reports on how a particular person's average telomere length compares, as a percentile of the population, to that of other persons of the same age and gender. This comparison is based upon TelomereDX having measured average telomere length on a statistically large number of people to construct a nationally representative population. TelomereDX has built a proprietary mathematical model that projects average telomere length for the typical person of a particular age and gender to the measured telomere length of the person taking the test.
- 29. The TeloYears<sup>TM</sup> test report on how a particular person's average telomere length compares as a percentile of the population to others of the same age and gender is therefore

highly reliable and accurate. This image is an example of the population comparison for a particular measured average telomere length:



(<a href="https://www.teloyears.com/html/pdf/TeloYears\_TestReport\_Final.pdf">https://www.teloyears.com/html/pdf/TeloYears\_TestReport\_Final.pdf</a> (excerpted)).

- 30. Finally, a person's cellular age, or "TeloYears," is determined based on mathematical modeling of the actual age of a typical man or woman whose telomere length is similar to that of the person being tested.
- 31. The TeloYears<sup>TM</sup> test therefore provides a reliable and accurate determination of a person's cellular age. This image is an example of the test report on both cellular age and actual age based on birthdate:



(https://www.teloyears.com/html/pdf/TeloYears TestReport Final.pdf (excerpted)).

## <u>Titanovo Surfaces as a Competitor that is Not Competing Fairly</u>

32. Recent comparisons in the press of TeloYears<sup>TM</sup> and Titanovo test results have

had the wholly unfair and unjustified consequence of casting doubt on the validation, reliability and accuracy of TeloYears<sup>TM</sup> test results. On May 25, 2017, the Center for Science in the Public Interest published an article entitled Can You Lengthen Your Telomeres to Live Longer? (hereafter "CSPI," available at https://cspinet.org/tip/can-you-lengthen-your-telomeres-livelonger), concluding, based on the difference between TeloYears<sup>TM</sup> and Titanovo test results, that "[t]elomere-measuring kits may not be reliable" and that it is "not clear that the tests produce accurate results." Similarly, approximately a week earlier, on May 19, 2017, author David Wagner published an article, podcast and YouTube video entitled These DNA Tests Promised to Tell Me How Well I'm Aging — My Results Didn't Add Up (hereafter "Wagner - KPBS," available at <a href="http://www.kpbs.org/news/2017/may/19/teloyears-titanovo-telomere-testing/">http://www.kpbs.org/news/2017/may/19/teloyears-titanovo-telomere-testing/</a>), which, based on having obtained different results from the TeloYears<sup>TM</sup> and Titanovo tests that "completely disagreed," sought to examine the companies' respective methodologies but ultimately professed to being "pretty confused." None of this made sense to TelomereDX, particularly in view of substantial time and resources that it has invested over the years developing proprietary and validated test methodologies, prompting it to investigate Titanovo. What TelomereDX discovered forms the basis for the recovery sought in this lawsuit. Titanovo artificially shortened the time to develop and launch its telomere measurement test by stealing TelomereDX's patented test methods, giving rise to the claims for patent infringement that are made in Count I. Apparently lacking robust and validated test procedures, models, standards and testing facilities, Titanovo has made false and misleading representations and omissions designed to overstate its professional certifications, capabilities and expertise, giving rise to federal and state law claims for false advertising, consumer fraud, and deceptive practices made in Counts II, V and VI. In addition, Titanovo has freeloaded on TelomereDX's brand and its TeloYears<sup>TM</sup>

mark, giving rise to claims for unfair competition and trademark infringement made in Counts III and IV and further supporting the state law claim for deceptive practices made in Count VI.

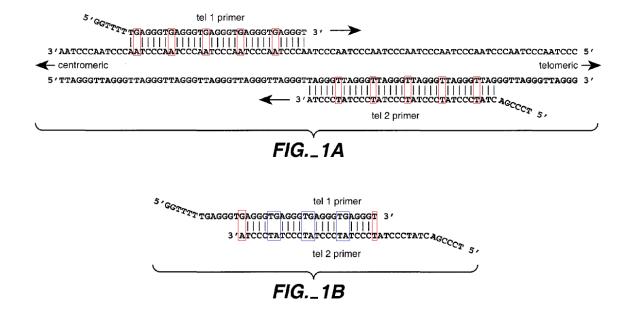
### **Titanovo Infringes '904 Patent**

#### '904 patent

- 33. The '904 patent discloses molecular biology methods for artificially increasing the number of target segments of human nucleic acids by several orders of magnitude using a certain type of polymerase chain reaction ("PCR") assay (the Cawthon qPCR assay as discussed above). The dramatic increase in the number of copies of target nucleic acids makes testing and analysis of the target nucleic acids easier. More specifically, the '904 patent discloses methods for amplifying repetitive units of human nucleic acids, e.g., telomeres, using PCR. The '904 patent thereby provides improved procedures for estimating telomere length, making these procedures less time consuming and reducing the quantities of DNA required for testing.
- 34. PCR provides a highly sensitive method for detecting the presence of target nucleic acids by selective amplification of the target nucleic acids. The PCR method relies on the use of oligonucleotide primers that hybridize to opposite ends of a target nucleic acid segment, an amplicon, and prime copying of the nucleic acid segment by a DNA polymerase. Reiterative rounds of DNA synthesis by the DNA polymerase, denaturation, and reannealing allows exponential amplification of a given target nucleic acid.
- 35. Primer selection is a major determinant in the success or failure of the amplification reaction for at least two reasons.
- 36. First, primers must hybridize with specificity to the target nucleic acid, but not hybridize to and amplify non-target nucleic acid sequences. In many instances, selective hybridization by primers is achieved by identifying unique regions of target nucleic acids that

allow design of a unique complimentary primer. This approach becomes difficult, however, when the target nucleic acids include tandem repetitive sequences such as telomere repeats because complementary primers will always have some degree of complementarity to multiple locations along the target nucleic acid sequence.

- 37. Second, the amplification of non-target nucleic acid sequences becomes problematic when the 3' end of a primer is complementary to another primer. In these situations, the primers will tend to hybridize to each other; those hybridized primers are then extended by the DNA polymerase to form "primer-dimer" products. Subsequent amplification of "primer-dimers" leads to depletion of primers, resulting in reduced sensitivity or even failure to amplify the intended target nucleic acid.
- 38. The methods disclosed and claimed by the '904 patent solve both these issues through the design of novel primers that enable specific targeting of nucleic acids with tandem repetitive sequences, such as telomere repeats, and the reduction of primer-dimer formations. The result is the exponential amplification of target nucleic acids with tandem repetitive sequences, like those found in telomeres.
- 39. By way of example, the sequence and hybridization schemes of primers disclosed and claimed by the '904 patent are shown in modified FIG. 1A, aligned with complementary strands of tandem repetitive sequences in telomere DNA, and in modified FIG. 1B, aligned with each other:



- 40. The "tel 1 primer" is shown hybridized to a complementary stretch of telomeric DNA oriented 5' to 3'. The "tel 2 primer" is shown hybridized to a complementary stretch of telomeric DNA oriented 5' to 3'. Notably, for each primer nucleotide residues are altered to produce mismatches between the altered residues and the nucleotide residues at the identical nucleotide positions of each repetitive unit as highlighted by the red boxes in FIG. 1A. Therefore, every sixth base is mismatched in FIG. 1A for both primers.
- 41. To limit primer-dimer products, the altered residues of each primer also produce a mismatch with the 3' terminal nucleotide residue of the other primer when the primers hybridize to each other as highlighted by the red boxes in FIG. 1B, thus blocking extension by the DNA polymerase. In addition, the altered residues of each primer produce a sequential internal nucleotide residue mismatch with the other primer when the primers hybridize to each other as highlighted by the blue boxes in FIG. 1B.
- 42. Additional primers claimed by the '904 patent are disclosed as SEQ ID NO.: 8 and SEQ ID. NO.: 9. SEQ ID. NO. 8 has the following specific sequence comprising 39 bases:

- 5'-CGGTTTGTTT GGGTTTGGGT TTGGGTTTGG GTTTGGGTT-3'. SEQ ID NO. 9 has the following sequence comprising 39 bases: 5'-GGCTTGCCTT ACCCTTACCC TTACCCTTAC CCTTACCCT-3'.
- 43. The '904 patent claims are directed to a method of amplifying repetitive units in a repetitive region of a human target nucleic acid comprising contacting a target nucleic acid (e.g., telomere) with primers that meet specific limitations and amplifying the target nucleic acid by a polymerase chain reaction. For example, SEQ. ID NO. 8 and SEQ ID NO. 9 are covered by the '904 patent claims and are specifically recited in claim 12a.

#### Titanovo Activities Infringing '904 Patent

- 44. Titanovo markets and sells online a Telomere Testing Kit at <a href="https://titanovo.com">https://titanovo.com</a>. The Telomere Testing Kit is described both on the site's home page and at the page for online orders, attached as Exhibits B and C, respectively. In addition, the Telomere Testing Kit is sold online at <a href="https://telomeres.titanovo.com">https://telomeres.titanovo.com</a>, where orders of the "telomere length testing service" offered for sale on the home page are directed (upon clicking on "Order Now") to the aforementioned page for online purchases of the Telomere Testing Kit.
- 45. Titanovo also markets and sells online a DNA Lifestyle Coach at both <a href="https://titanovo.com">https://titanovo.com</a> and https://dnalifestyle coach.com, at Exhibits D and E, respectively. The DNA Lifestyle Coach process is described as including "Collect DNA at home" and "Send to us." The DNA Lifestyle Coach provides "DNA Lifestyle Coach panels," one of which is "Telomeres." As described on the attached Exhibit F, the Telomere panel offered by Titanovo provides "your telomere length test," and the test provides the same telomere measurement results in substantially the same or similar form as the Telomere Testing Kit. See Exhibits G and H. On information and belief, the telomere test offered with DNA Lifestyle Coach is the same as

that of the Telomere Test Kit and/or uses the same methods to derive the same or substantially similar results as that of the Telomere Test Kit.

46. Titanovo, upon receiving an online order and payment for the telomere tests provided by the Telomere Test Kit or the DNA Lifestyle Coach, delivers by priority mail a test directly to the consumer. The following image is representative of the test kit.



(Titanovo/Kit #41001703074757-Pkg).

47. The contents of the kit include written instructions, a nylon swab, a vial for collecting the specimen, a recloseable zipper lock bag, and a prepaid return envelope. The following image is representative of the test kit.



(Titanovo/Kit #41001703074757- Contents).

48. The consumer is instructed to create an account on dnalifestylecoach.com for purposes of registering the kit with the fourteen digit sample number affixed both to the outside of the kit and vial. The following images are representative of the sample number:



49. The consumer is further instructed to use the nylon swab for obtaining saliva from the inner cheek, place the swab in the vial, place the vial in the bag, and then place the bag in the prepaid return envelope. The sample is then delivered by first class mail to Titanovo's office in

North Carolina, as reflected in the attached representative prepaid return envelope.



(Titanovo/Kit #41001703074757-Envelope).

- 50. Based on the delivery instructions provided with the Telomere Testing Kit, and based on representations that Titanovo has made in the past on its website, Titanovo is, on information and belief, analyzing and testing at least some portion of consumers' saliva swabs in-house.
- 51. Titanovo also, on information and belief, out-sources the analysis and testing of some portion of consumers' saliva swabs to third-party laboratories. Titanovo has in the past made representations to this effect on its website. In addition, since CLIA certification is required of any laboratory accepting human DNA samples for testing, and since Titanovo does not have this certification (notwithstanding its representations to the contrary, see paragraphs 60 to 76, below), it would need to outsource its tests in order to comply with federal law.
- 52. Upon completion of the test, the consumer receives notice by email that he or she can go online to see the results at dnalifestylecoach.com.
- 53. Titanovo represents that ("Our kit is able to tell users") the test results provided to the consumer will include: 1) "Their telomere length measured in relative T/S and in absolute length in kbp (kilobasepairs);" 2) "The dynamics of telomere length change overtime by doing

consequent tests;" [sic] 3) "How their telomere length compares with others in their demographic (age, sex):" and 4) "How their telomere length compares with others who have similar and different diets." These representations are, among other places, made on its website at: https://titanovo.com/product/telomere-testing-kit-one/.

- 54. In addition to direct-to-consumer sales, Titanovo also offers bulk pricing to third-party distributors who wish to sell the Titanovo Telomere Test Kit and DNA Lifestyle Coach. In response to FAQ "How May I Distribute Titanovo Products?" Titanovo states that it "is glad to offer bulk pricing for distributors who wish to offer our products in new markets." (https://titanovo.com/faqs/).
- 55. Titanovo's website provides a "technical whitepaper" to persons interested in receiving "a detailed description of your method" and the "full details on the methodology and applications" used to support its "Telomere Testing Kit" and its "DNA Lifestyle Coach" as shown in Exhibit I.
- 56. A true and correct copy of Titanovo's technical whitepaper is attached as Exhibit J. The technical whitepaper discloses that Titanovo uses the "method of O'Callaghan (Biotechniques 2008, Vol 44, No. 6, pp 807-809) . . . to estimate both the mean telomere length per reaction and the mean genome copies for each sample." Titanovo's technical whitepaper further confirms that the "telomere length per diploid genome and the length per telomere are then calculated according to the O'Callaghan method."
- 57. Attached as Exhibit K is a true and correct copy of the O'Callaghan paper that Titanovo relies on for its method of measuring telomere length. The O'Callaghan paper is based on the Cawthon qPCR assay and the '904 patent. O'Callaghan "describes the development of a

simple and reproducible method to measure absolute telomere length [] [b]ased on Cawthon's quantitative real-time PCR (qRT-PCR) assay." Dr. Cawthon is the inventor of the '904 patent that discloses and claims the Cawthon qPCR assay.

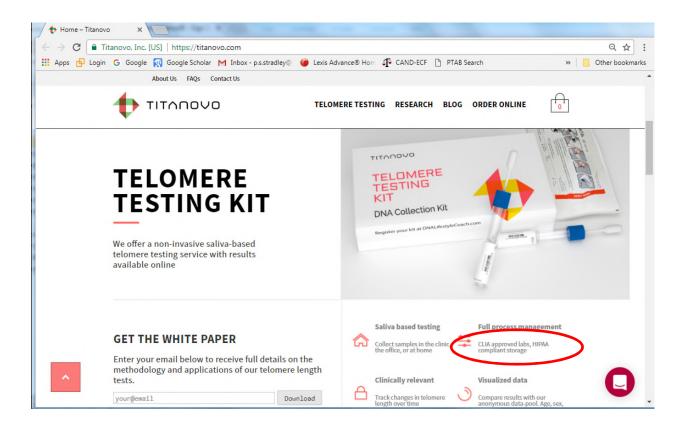
- 58. The O'Callaghan paper performs the Cawthon qPCR assay disclosed and claimed by the '904 patent. "Quantitative real-time amplification of the telomere sequence was performed as described by Cawthon (5)" with modifications that are irrelevant to the '904 claims. The O'Callaghan paper specifically discloses the primers used for amplification of telomeres as a "telomere forward primer" and a "telomere reverse primer." The "telomere forward primer" has the following sequence: "CGG TTT GTT TGG GTT." This is the primer disclosed and claimed in the '904 patent as SEQ ID.

  NO. 8. The "telomere reverse primer" used by the method of O'Callaghan has the following sequence: "GGC TTG CCT TAC CCT TAC CCT TAC CCT TAC CCT." This is the primer disclosed and claimed in the '904 patent as SEQ ID. NO. 9.
- 59. Titanovo's "technical whitepaper" confirms it is using the Cawthon qPCR assay to directly or indirectly infringe the '904 patent by amplifying telomere DNA in support of its "Telomere Testing Kit" and its "DNA Lifestyle Coach" products.

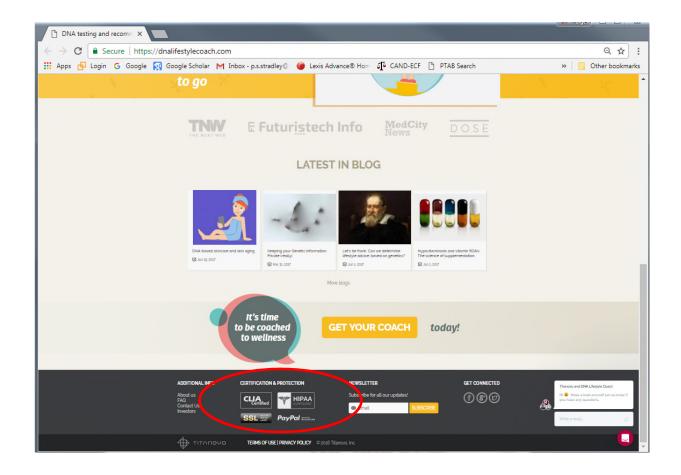
### **Titanovo's False Advertising**

- 60. Titanovo has been misrepresenting the reliability and viability of its method of applying the Cawthon qPCR assay as well as deriving other data such as population comparisons or what it describes as biological age.
- 61. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) require clinical laboratories to be certified by the Centers for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

62. Apparently recognizing the importance of being CLIA certified, Titanovo repeatedly states that it has the certification. Titanovo's current website for its telomere testing kits and DNA Lifestyle Coach products, <a href="www.titanovo.com">www.titanovo.com</a>, states that it is CLIA certified:

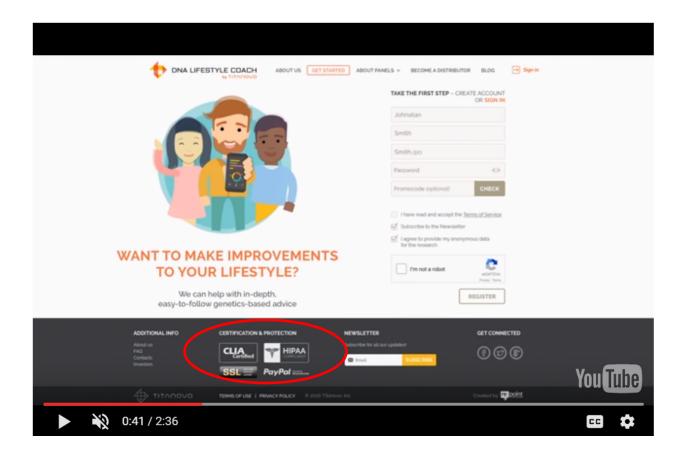


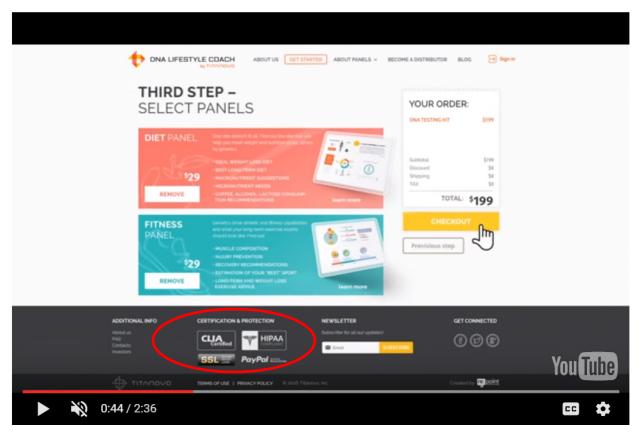
63. Titanovo's current website for its DNA Lifestyle Coach product, www.dnalifestylecoach.com, also states that it is CLIA certified:



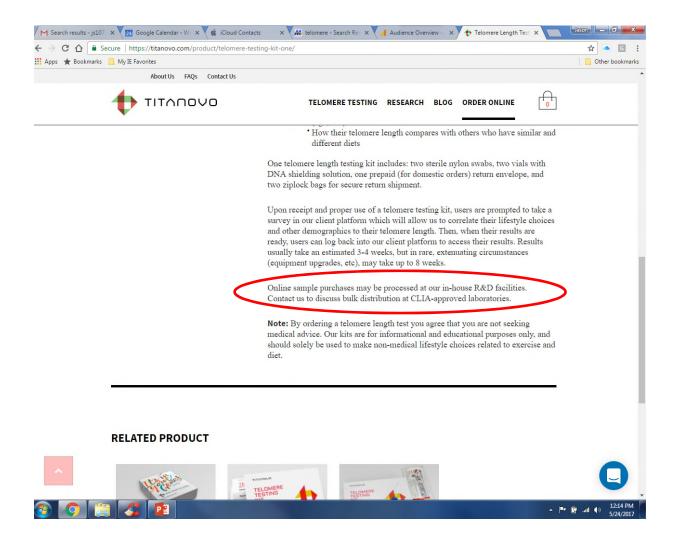
64. And in a video found on Titanovo's crowd funding page,

https://www.indiegogo.com/projects/titanovo-measure-your-health-lifestyle--3#/, Titanovo again identifies itself as CLIA certified:

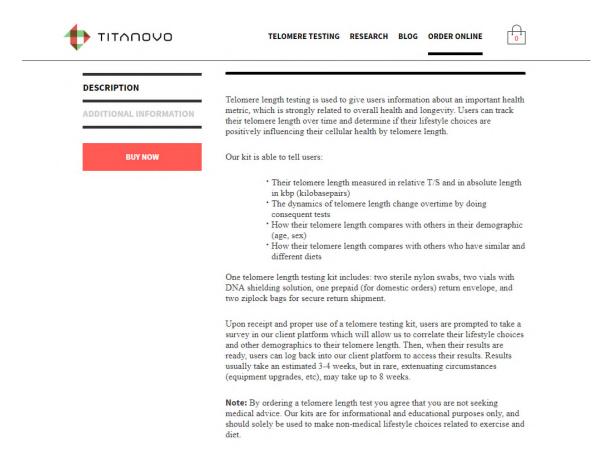




- 65. Titanovo's representations, in conjunction with advertising and sales of its telomere testing kit and DNA Lifestyle Coach products, that it is CLIA certified is literally or impliedly false. Titanovo is not a CLIA certified laboratory according to the registries maintained by the Centers for Medicare and Medicaid Services.
- 66. That Titanovo's misrepresentations that it has CLIA certification are false is further evidenced by Titanovo's efforts to sanitize its website of admissions that it is not CLIA certified. On information and belief, as recently as May 2017, Titanovo's website included the following statements:



But Titanovo has since removed that statement. The same page on its website now reads as follows:



67. Upon information and belief, Titanovo removed from its website statements differentiating its "in-house" capabilities from "CLIA-approved laboratories" with full knowledge and with the intent of concealing, suppressing, or omitting this information from its website and, thereby, withholding accurate information on its certification from its consumers. The omission wrongly creates a likelihood of confusion among consumers and causes them to hold the erroneous impression that Titanovo is CLIA certified. The omission manifests Titanovo's recognition that it is material to potential consumers of genetic tests to determine

telomere length to know whether the companies providing these tests are performing the tests in their own facilities, and whether the companies providing these tests are CLIA certified.

- 68. Titanovo also withholds from consumers and misrepresents the fact that third-party laboratories, at least sometimes, perform the testing and analysis of swabs from the packaging and information provided in its actual kits. See par. 67, above. The packaging and information provided in the kits instructs consumers to send the swabs to Titanovo in North Carolina and does not indicate that the swabs are, at least sometimes, later sent to third-party laboratories. (*Id.*) Titanovo's packaging misrepresents to consumers that Titanovo tests and analyzes all swabs in-house.
- 69. Titanovo's omission (i.e., its failure to state that a third-party, at least sometimes, analyzes and tests the swabs) is likely to confuse consumers and cause them to hold the erroneous impression that Titanovo tests and analyzes all swabs in-house. Consumers are thereby denied notice of, and the opportunity to investigate, third-party testing facilities, including without limitation whether and to what degree these third-party facilities have the appropriate expertise, capabilities, and certifications such as that required by CLIA.
- 70. The likely confusion and deception of consumers due to Titanovo's false statements and omissions is compounded because Titanovo makes statements that further imply that it is CLIA certified and that it performs all tests in-house. For example, Titanovo describes its tests on <a href="www.titanovo.com">www.titanovo.com</a> as "simple test-reliable scientific results" and states that consumers will get "guaranteed scientific results." Consumers are likely to take these statements as confirmation that Titanovo is CLIA certified and that all saliva swabs are tested in-house.
- 71. TelomereDX is harmed by Titanovo's concealment, suppression, or omission which implies to consumers that Titanovo—without involvement of third-party laboratories—is

testing and analyzing consumers' swabs. Titanovo's omission is likely to mislead people into thinking that they are getting reliable and accurate results when this may or may not be true. The omission dissuades consumers from investigating or questioning the reliability and accuracy of Titanovo's test both before and after purchase. The omission also induces consumers to move forward with purchasing a Titanovo testing kit because consumers have no reason to question the quality of testing and analysis or to think that Titanovo's results would be of a lesser quality than TelomereDX's. Upon information and belief, it is material to a consumers' purchasing decisions to know (or not know) whether third-party laboratories, which may or may not be CLIA certified and which may or may not be located in the United States, performed the relevant testing and analysis.

- 72. Titanovo's literal or impliedly false statements and/or misrepresentation by omission that it is CLIA certified harms TelomereDX who is, in fact, CLIA certified. Upon information and belief, CLIA certification influences a consumer's purchasing decisions. For example, upon wrongly believing that Titanovo is CLIA certified, consumers are likely to believe that Titanovo's products and services are of high quality and that its results are accurate and reliable. Consumers are also likely to believe that the accuracy and reliability of the two parties' test results are the same when, in fact, the quality, including accuracy and reliability, may not be equal. Consumers who use both parties' testing kits and receive inconsistent results are likely to assume neither kit is accurate or reliable and may refrain from purchasing any kits in the future. This results in potential lost sales to TelomereDX and harms TelomereDX's reputation, as well as the telomere testing industry's reputation as a whole.
- 73. The CPSI (Can You Lengthen Your Telomeres to Live Longer?) and Wagner-KPBS (These DNA Tests Promised to Tell Me How Well I'm Aging — My Results Didn't Add

*Up*) articles are examples of the consumer confusion and the harm to TelomereDX's reputation and the telomere testing industry's reputation as a whole caused by Titanovo's false or misleading advertising and unfair competition. See paragraphs 7 and 32, above.

- 74. The Wagner-KPBS article demonstrates that Titanovo misrepresented to the author a) that "both companies" are CLIA certified when in fact this is only true as to TelomereDX and b) that Titanovo performs all testing in-house where this contradicts, among other things, statements Titanovo made on its website and later removed. In addition, the author of the Wagner-KPBS article says that he got conflicting results upon taking both the TeloYears<sup>TM</sup> and Titanovo tests, leading him to question the reliability of both tests and telomere testing in general, and, unfortunately for TelomereDX, causing him to hold the impression that both tests are of low quality and low reliability.
- 75. The CPSI concludes based on conflicting test results that "[t]elomere-measuring kits may not be reliable" and that it is "not clear that the tests produce accurate results."

  Notwithstanding the significant differences between TelomereDX and Titanovo in terms of their facilities, expertise, validated results and models, and transparency, the article lumps them together and quotes the alleged criticism of both companies by a purported expert: "The laboratory method that *companies like these* employ is the easiest to use, but *the least reliable*." (Emphasis added).
- 76. Judicial intervention is required to remedy and otherwise prevent the substantial and, in many respects, irreparable harm caused by Titanovo's false advertising and unfair competition to TelomereDX's reputation and business interests.

### **Titanovo's Trademark Infringement**

- 77. The harm to TelomereDX's reputation is further exacerbated by Titanovo's use of TelomereDX's trademark TELOYEARS in its internet advertising as a method of unfairly drawing consumers to its website.
- 78. TelomereDX owns the federal trademark application for the trademark TELOYEARS (serial no. 87270168) and has common law rights in the trademark TELOYEARS in association with use in DNA testing for humans; chemistry services, namely, chemistry-based testing services for scientific purposes, namely, testing in the field of molecular diagnostics; genetic testing for scientific purposes; providing scientific analysis and informational reports based upon results of laboratory testing in the field of DNA testing; scientific research in the field of DNA testing; chemistry services, namely, chemistry-based testing services for medical purposes, namely, molecular diagnostics testing services; and DNA testing for medical purposes. TELOYEARS is distinctive for the above described goods and services, and TelomereDX has been using the mark continuously in commerce in association with the above goods and services since at least as early as August 3, 2016.
- 79. TelomereDX has invested significant time and expense in promoting its products and services under the TELOYEARS mark and developing a reputation for providing high quality goods and services under that mark. As a result, TelomereDX's customers across the country use and rely on the TELOYEARS mark to identify the goods and services offered by TelomereDX; the TELOYEARS mark is recognized and relied upon as identifying TelomereDX as the sole source of products and services for consumers and as distinguishing TelomereDX's products and services from those of others. The TELOYEARS mark has acquired substantial goodwill and is a valuable commercial asset.

- 80. Titanovo has and continues to trade off of the goodwill of TelomereDX's TELOYEARS trademark.
- 81. Internet search engines (e.g., Google, Yahoo!, AltaVista, MSN, AOL, etc.) enable consumers to locate specific companies and the online websites of those companies by keying in terms and performing searches of search engine databases. After a consumer keys in a search term (e.g. "shoes"), the search engine processes the request and produces search results matching the key term searched (e.g., "NIKE.com"). The process of conducting a key term search on a search engine is nearly instantaneous, which allows consumers to rapidly key in a search term, view results of that query, select a destination, and arrive at the website of the selected company.
- 82. Internet search engines produce at least two types of search results: organic and sponsored. Organic search results are based on data collected by search engines from the Internet. Search engines use crawlers, spiders, and other technology to learn and collect information from various websites located on the Internet. Those results are then collected in a database. If a key term entered by a consumer matches the data collected from a particular website, that website may be produced as a search result.
- 83. Sponsored search results are links that are based on keywords purchased by advertisers. Several search engines have set up sponsored link programs as a way to generate revenue for the search engines and enable advertisers to reach additional consumers. As part of a sponsored link program, advertisers purchase or bid on terms. Those terms are then linked to the advertiser's advertisement, which contains a link to the advertiser's desired Internet address or website.

84. A keyword advertisement is generally composed of a header, a description, and a link. Advertisers fill in each section of the advertisement when signing up for the advertisement placement. A typical ad with its component parts is shown below:



- 85. If a consumer keys in an advertiser's purchased term (e.g, "teloyears" for the example above), the advertiser's advertisement and website link will appear on the search results page. The more advertisers who bid on a particular term, the higher price the search engines charges for placement of the advertisement.
- 86. One example of a sponsored link program is Google, Inc.'s AdWords program. The AdWords program enables advertisers to purchase or bid on keywords that generate an advertising link (called a "Sponsored Link") on the search results page. The Sponsored Link directs consumers to the advertiser's website or advertisement.
- 87. By placing a competitor's trademark in keyword advertisements, advertisers trick consumers into believing that the advertiser's products or services are in some way related, endorsed, sponsored by, or affiliated with the competitor or the competitor's trademark.
- 88. Because of the ease of conducting a search and the speed of the search results, consumers may click on the competitor's website, many of whom do not realize they have clicked on the link to a company unrelated to the term placed in the search engine query box.
- 89. Titanovo was given notice of TelomereDX's TELOYEARS mark through use of the TM symbol in connection with TelomereDX's trademark and via TelomereDX's application for federal registration. Upon information and belief, based in large part of Titanovo's efforts to

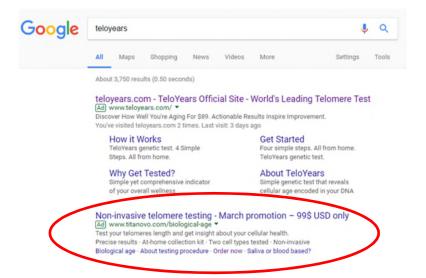
directly benefit from the commercial value of the TELOYEARS mark as set forth below,

Titanovo had actual knowledge of TelomereDX's rights in the TELOYEARS mark and were

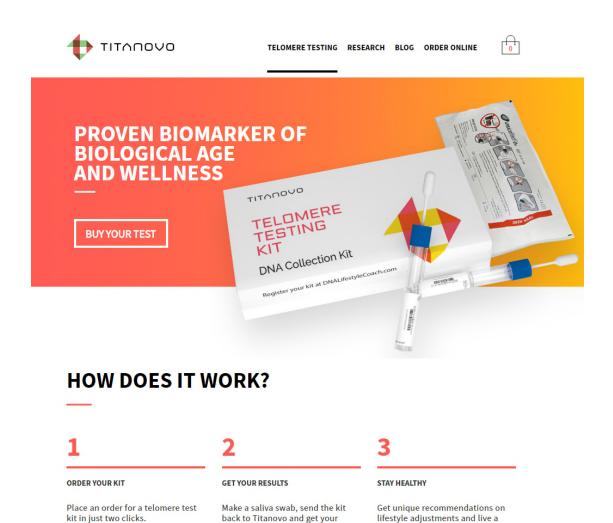
fully aware that their actions violated TelomereDX's rights. And Titanovo has had actual notice

of TelomereDX's rights in the TELOYEARS mark since at least the filing of this Complaint.

90. After TelomereDX began use of its distinctive TELOYEARS mark, Titanovo began incorporating the TELOYEARS mark in connection with its advertising, promotion, and marketing of competing products. In particular, upon information and belief, Titanovo purchased and continues to purchase TELOYEARS as a keyword on Google's AdWords program as shown in the screen capture below:



- 91. Titanovo's Chief Operating Office Corey McCarren is identified as the registrant contact and administrative contact for the website <a href="www.titanovo.com">www.titanovo.com</a>, see attached Exhibit L, and, upon information and belief, Titanovo maintains and operates <a href="www.titanovo.com">www.titanovo.com</a>.
- 92. By placing the TELOYEARS mark in its advertisements, Titanovo sought and continues to seek to trick consumers into visiting its website www.titanovo.com, which offers for sale, directly to consumers, products and services which directly compete with TelomereDX's TeloYears<sup>TM</sup> test:



93. Titanovo's use of the TELOYEARS mark in online advertisements is in interstate commerce, including Delaware, and is likely to cause confusion, mistake, or deception as to the source of origin of Titanovo's products and services in that consumers and/or potential consumers are likely to believe that the products and services offered by Titanovo are provided by, sponsored by, approved by, licensed by, affiliated or associated with, or in some way legitimately connected to TelomereDX.

results.

healthy life.

94. Once consumers click on Titanovo's advertisement, the consumers are taken to Titanovo's website, which sells the same, similar, or related products to that offered by

TelomereDX. Consumers are thus directed away from TelomereDX's website and directed to Titanovo's website.

- 95. Even if consumers eventually realize that Titanovo's website and the goods and services offered by Titanovo are not provided by, sponsored by, approved by, etc. TelomereDX, those consumers are still likely to experience initial interest confusion to the detriment of TelomereDX. For example, the misdirected consumers is likely to choose to purchase a product from Titanovo rather than one from TelomereDX because of the convenience of already being on Titanovo's website. Due to the nature of the product and services being sold, which allow individuals to purchase testing kits to track any improvements to biological health over time, an initial lost sale could result in the lost sale of numerous future sales to the same consumer.
- 96. In addition consumers who are displeased with the quality of Titanovo's products and services or the accuracy and reliability of its results may opt to not purchase telomere testing kits again, thus foreclosing the possibility of TelomereDX later obtaining that sale and harming the reputation of the telomere testing industry as a whole, including that of TelomereDX.
- 97. TelomereDX has been harmed and will continue to be harmed by Titanovo's actions infringing TelomereDX's trademark rights unless Titanovo is permanently enjoined.

#### **COUNT I: INFRINGEMENT OF '904 PATENT**

98. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraph 1 through 97 above.

### **Direct Infringement**

- 99. Titanovo has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more of claims of the '904 patent by, among other things, making, using, importing, offering for sale, or selling its Telomere Testing Kit and DNA Lifestyle Coach and the methods supporting the "non-invasive saliva-based telomere testing service" provided therewith, which are covered by at least claims 1, 2, 3, 4, 5, 6, 7, 10, 12, 13, 14, and 15 of the '904 patent.
- 100. Titanovo's technical whitepaper explains that it uses the "method of O'Callaghan . . . . to estimate both the mean telomere length per reaction and the mean genome copies for each sample." The O'Callaghan paper discloses its "method is based on Cawthon's quantitative real-time PCR (qRT-PCR) assay" and that the "[q]uantitative real-time amplification of the telomere sequence was performed as described by Cawthon" with minor modifications. Titanovo therefore practices the methods of claims 1, 2, and 10.
- 101. The O'Callaghan paper further discloses the specific qRT-PCR reaction conditions and components it used for its reactions, including its use of the primers recited by claim 12 of the '904 patent, and cites to Cawthon. Titanovo therefore practices the methods of claims 3, 12, and 14.
- 102. The O'Callaghan paper states that telomeres are composed of "long hexamer (TTAGGG) repeats." Titanovo therefore practices the method of claim 7.
- 103. The O'Callaghan paper discloses "a single copy gene, 36B4... was used as a control for amplification for every sample performed, as described by Cawthon" and that this "data was used for the relative measure, but was also essential for the absolute method to

quantify the amount of DNA or number of genomes in each well." Titanovo therefore practices the methods of claims 13 and 15.

- 104. A comparison of the primer nucleotide sequences used by the O'Callaghan paper to the hexamer repeats of telomeres reveals that each primer has a 5' terminal sequence that does not hybridize to telomere repeats and at least one primer has mismatches at non-adjacent nucleotide positions when hybridized to telomeres. Titanovo therefore practices the methods of claims 4 and 6.
- 105. A comparison of the primer nucleotide sequences used by the O'Callaghan paper to each other reveals at least two adjacent nucleotide mismatches in the complex formed by hybridization of the two primers with each other. Titanovo therefore practices the method of claim 5.

#### **Induced Infringement**

- 106. Titanovo has infringed and continues to infringe indirectly by active inducement, specifically intending its third-party laboratories and distributors to directly infringe one or more claims of the '904 patent.
- 107. Since at least the date of service of this Complaint, Titanovo has had actual knowledge of the '904 patent, as well as knowledge that its Telomere Testing Kit and its DNA Lifestyle Coach are used to practice the methods claimed and taught in the '904 patent.
- 108. With this knowledge, Titanovo knowingly has induced, and continues to induce, direct infringement by third-party laboratories that have been and are continuing to test the saliva swabs submitted by consumers using the Telomere Testing Kit and the DNA Lifestyle Coach. Titanovo, upon receiving saliva swabs from consumers, knowingly outsources at least some of them to third-party laboratories to be tested to determine telomere length. Upon information and

belief, Titanovo has entered into a contractual relationship with these third-party laboratories to provide these telomere testing services. Based on Titanovo's representations in the technical whitepaper describing its testing methods, see Ex. J, "all samples" are tested according to the same methods, and there is no variation between tests performed in-house as compared to those outsourced to third-party labs. Therefore, where Titanovo has engaged third-party laboratories to test consumer saliva swabs, it has, on information and belief, directed and instructed of them to use the same methods that Titanovo uses when it tests the samples in-house, and, consequently, Titanovo has intentionally caused, urged, encouraged or aided action by its third-party laboratories to practice the methods claimed and taught in the '904 patent resulting in direct infringement.

laboratories practice the methods claimed and taught in the '904 patent. In its technical whitepaper, see Ex. J, expressly refers to and states that it relies upon the "method of O'Callaghan" to determine telomere length and this method is covered by one or more claims of the '904 patent. According to Titanovo, determination of telomere length using this method is relevant to biological age, disease risk, cancer, and overall health, and Titanovo touts that its products provides consumers with telomere length which can be improved through diet, exercise, and other lifestyle adjustments. The purpose of Titanovo's product—to provide consumers with telomere length and, thus, insight into their health and potential tracking and improvement of that health—would be frustrated if the third-party laboratories did not analyze and test consumers' saliva swabs in accordance with the patented method because the patented method provides improved procedures for estimating telomere length. The purposes of the Telomere Testing Kit

and DNA Lifestyle Coach therefore confirms Titanovo's intent that third-party laboratories use the methods and claims taught in the '904 patent.

110. Titanovo's knowing and intended direction to others, including its third-party laboratories, is causing indirect infringement under 35 U.S.C. § 271(b) of one or more of claims 1, 2, 3, 4, 5, 6, 7, 10, 12, 13, 14, and 15 of the '904 patent.

## Willful Infringement, Damages and Injunctive Relief

- 111. The infringement of the '904 patent by Titanovo has been, since at least the date of service of this Complaint, and continues to be, deliberate, willful, and knowing, or with deliberate indifference, entitling TelomereDX to treble damages.
- 112. TelomereDX has been, and continues to be, damaged and irreparably harmed by the infringement of Titanovo, which will continue unless this Court enjoins Titanovo and those acting on its behalf or under its control.
- 113. TelomereDX, under 35 U.S.C. § 284, seeks damages adequate to compensate for the infringement of Titanovo.
- 114. As a consequence of Titanovo's willful infringement of the '904 patent, TelomereDX is entitled to enhanced damages pursuant to 35 U.S.C. § 284.
- 115. The Court should declare this an exceptional case under 35 U.S.C. § 285, entitling TelomereDX to recover attorneys' fees.

# COUNT II: FALSE ADVERTISING UNDER THE LANHAM ACT (15 U.S.C. § 1125)

116. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraphs 1 through 115 above.

- 117. In conjunction with sales, offers for sale, and advertisements of its Telomere
  Testing Kit and its DNA Lifestyle Coach products, Titanovo makes literally or impliedly false
  statements in interstate commerce, including through omission, that it is CLIA certified.
- 118. In conjunction with sales, offers for sale, and advertisements of its Telomere Testing Kit and its DNA Lifestyle Coach products, Titanovo also makes literally or impliedly false statements in interstate commerce, including through omission, that it always performs its own testing and analysis of consumers' saliva swabs.
- 119. Upon information and belief, Titanovo's false statements and omissions are material to consumers and are likely to confuse, mislead, or deceive consumers.
- 120. Titanovo's false statements and omissions have harmed and will continue to harm TelomereDX.
- 121. TelomereDX is entitled to recover actual and treble damages, attorneys' fees, and the costs of this litigation pursuant to 15 U.S.C. § 1117 and injunctive relief pursuant to 15 U.S.C. § 1116.

# COUNT III: UNFAIR COMPETITION UNDER THE LANHAM ACT (15 U.S.C. § 1125)

- 122. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraphs 1 through 121 above.
- 123. TelomereDX has common law rights in the mark TELOYEARS and has used the mark in commerce in the United States since August 3, 2016.
- 124. Upon information and belief, Titanovo's use in commerce of the mark TELOYEARS began after use by TelomereDX, and, upon information and belief, from the time of Titanovo's first use through present Titanovo has been aware of the vast goodwill and reputation represented and symbolized by TelomereDX's TELOYEARS mark.

- 125. Upon information and belief, Titanovo is also aware that TelomereDX's consumers and potential consumers rely upon TelomereDX's TELOYEARS mark as identifying TelomereDX's goods and services, and as distinguishing TelomereDX's goods and services from others.
- TelomereDX and is likely to cause confusion, including initial interest confusion, due to the similarity of goods and services offered in connection with the TELOYEARS mark and due to the fact that TelomereDX's and Titanovo's goods and services are advertised and promoted in the same channels of trade. Both parties advertise, promote, and offer their products and services to consumers in Delaware and across the United States, including through websites located on the internet. Both parties' advertising and promotional materials are directed to individual consumers rather than wholesalers, resellers, bulk buyers, etc.
- 127. Titanovo has acted and continues to act without regard to TelomereDX's property rights, and Titanovo's continued use of the TELOYEARS mark is likely to diminish the goodwill associated with TelomereDX's TELOYEARS mark.
- 128. As a result of Titanovo's unauthorized use of the TELOYEARS mark, Titanovo is being unjustly enriched at TelomereDX's expense, and TelomereDX is being damaged. And as a direct and proximate result of the likely confusion, mistake, or deception caused by Titanovo, TelomereDX has suffered and will continue to suffer irreparable harm if the conduct of Titanovo is not enjoined. TelomereDX has no adequate remedy at law.
- 129. The acts of Titanovo complained of herein constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and its actions have been in bad faith, with malice, or with knowledge.

130. TelomereDX is entitled to recover actual and treble damages, attorneys' fees, and the costs of this litigation pursuant to 15 U.S.C. § 1117 and injunctive relief pursuant to 15 U.S.C. § 1116.

# COUNT IV: TRADEMARK INFRINGEMENT UNDER DELAWARE STATE LAW (DEL. CODE ANN. TIT. 6, § 3301 ET SEQ.)

- 131. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraphs 1 through 130 above.
- 132. Titanovo uses the TELOYEARS mark in connection with the offering for sale and advertising of its goods and services in Delaware and in the United States. Such use is without TelomereDX's consent and is likely to cause confusion or to deceive consumers as to the source or origin of Titanovo's goods or services, including causing initial interest confusion.
- 133. Upon information and belief, Titanovo used the TELOYEARS mark with knowledge that its use would cause confusion or deceive consumers.
- 134. TelomereDX is entitled to damages, profits, and injunctive relief pursuant to DEL. Code Ann. tit. 6, § 3312-3314.

## COUNT V: CONSUMER FRAUD UNDER DELAWARE STATE LAW (DEL. CODE ANN. TIT. 6, § 2511 ET SEQ.)

- 135. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraphs 1 through 134 above.
- 136. In connection with the advertising and/or sale of its Telomere Testing Kit and its DNA Lifestyle Coach, Titanovo made false, misleading, or deceptive statements or concealed, suppressed, or omitted material facts including that (a) Titanovo is CLIA certified; and (b) Titanovo always tests and analyzes consumers' saliva swabs in-house rather than, at least sometimes, sending those swabs to a third-party laboratory.

- 137. Upon information and belief, Titanovo intended that consumers and others would rely upon its statements, concealment, suppression, or omission.
- 138. TelomereDX is entitled to injunctive relief and any other relief necessary to restore it pursuant to Del. Code Ann. tit. 6, § 2523.

# COUNT VI: DECEPTIVE TRADE PRACTICES UNDER DELAWARE STATE LAW (DEL. CODE ANN. TIT. 6, § 2531 ET SEQ.)

- 139. TelomereDX repeats, realleges, and incorporates hereunder by reference the allegations contained in paragraphs 1 through 138 above.
- 140. Titanovo has engaged in deceptive trade practices through its unauthorized use of TelomereDX's TELOYEARS mark and through its false, misleading, or deceptive statements or concealment, suppression, or omission of material facts including that (a) Titanovo is CLIA certified; and (b) Titanovo always tests and analyzes consumers' saliva swabs in-house rather than, at least sometimes, sending those swabs to a third-party laboratory.
- 141. Titanovo's actions—unauthorized use of TelomereDX's TELOYEARS mark and its false, misleading, or deceptive statements or concealment, suppression, or omission of material facts—individually or taken together are likely to cause confusion, deception, or misunderstanding and violate DEL. CODE ANN. tit. 6, § 2532(a)(1)-(3), (5), (7)-(8), and (12).
- 142. TelomereDX is entitled to damages, trebled, attorneys' fees and costs for Titanovo's willful conduct, and to injunctive relief pursuant to DEL. CODE ANN. tit. 6, § 2533.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that this Court enter:

1. A decree preliminarily and permanently enjoining Defendant, its principals, officers, directors, employees, agents, successors, assigns, and all persons in active concert with it:

- a. from infringing, and contributing to or inducing others to infringe, the '904 patent, including without limitation immediately ceasing any and all use of the Cawthon qPCR assay and any other methods protected as inventions in the '904 patent, pursuant to 35 U.S.C. § 283.
- b. from making false and misleading statements in violation of the Lanham Act and Delaware state law, including without limitation from making any direct or indirect representation that Titanovo is CLIA certified or that Titanovo is performing any tests or analyses in its own laboratory or facility, pursuant to 15 U.S.C. § 1116 and Del. Code Ann. tit. 6, §§ 2523, 2533.
- c. to affirmatively publish and disclose both the identity of any third-party facility performing any tests or analyses for Defendant and for each such third-party whether and to what extent they are CLIA certified and/or otherwise have professional certifications or licenses, pursuant to 15 U.S.C. § 1116 and DEL. CODE ANN. tit. 6, §§ 2523, 2533.
- d. from infringing TelomereDX's rights in the mark TELOYEARS, including without limitation using the mark to purchase keywords or other online advertising or ad placement, pursuant to 15 U.S.C. § 1116 and DEL. CODE ANN. tit. 6, §§ 3312-3314.
- e. from continuing to use ad placements using the mark TELOYEARS, pursuant to 15 U.S.C. § 1116 and Del. Code Ann. tit. 6, §§ 2533, 3312-3314.
- f. from engaging in any deceptive trade practices, pursuant to DEL. CODE ANN.tit. 6, § 2533;

- 2. A judgment in favor of Plaintiff that Defendant has infringed, contributed to, and/or induced the infringement of one or more claims of each of the '904 patent;
- 3. A judgment and order requiring Defendant to pay Plaintiff its damages, costs, expenses, and prejudgment and post-judgment interest for Defendant's infringement of the '904 patent as provided under 35 U.S.C. § 284;
- 4. An award to Plaintiff for enhanced damages resulting from the knowing, deliberate, and willful nature of Defendant's prohibited conduct with notice being made at least as early as the date of the filing of this Complaint, as provided under 35 U.S.C. § 284;
- 5. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiff its reasonable attorneys' fees;
- 6. A judgment and order requiring Defendant pay TelomereDX's damages, treble damages, attorneys' fees, and the costs for false advertising, unfair competition, and deceptive trade practices pursuant to 15 U.S.C. § 1117 and DEL. CODE ANN. tit. 6, § 2533;
- 7. A judgment and order requiring Defendant pay TelomereDX's damages and profits pursuant to DEL. CODE ANN. tit. 6, §§ 3312-3314; and

8.	Any and all other relief to which Plaintiff may show itself to be entitled.
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#### **DEMAND FOR JURY TRIAL**

Plaintiff, under Rule 38 of the Federal Rules of Civil Procedure, requests a trial by jury of any issues so triable by right.

Respectfully submitted,

Dated: July 14, 2017 By:\_\_/Patricia Smink Rogowski/\_

Patricia Smink Rogowski (Del. Bar No. 2632)

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